

**AMENDMENTS TO THE CLAIMS:**

The listing of claims will replace all prior versions, and listings of claims in the application:

**Listing of Claims:**

1 – 61. (canceled).

62. (currently amended) A process for making a microcellular polyhipe polymer scaffold which comprises polymerizing in a first stage forming different a-high internal phase emulsions (HIPEs) of an immiscible dispersed phase in a continuous phase, wherein the dispersed phase is void or contains dissolved or dispersed materials, and (co)monomers, oligomers and/or pre-polymers are present in the continuous phase, by introducing the dispersed phase by controlled dosing into the continuous phase with controlled mixing at controlled emulsification temperature and rate to achieve ~~an~~ emulsions of controlled pore size, and in a second stage subsequently-homogenizing for controlled period under controlled deformation, in a third stage co-extrusion of polyhipe emulsions providing different pore and interconnect sizes on polymerization and in a fourth stage polymerizing under controlled temperature and pressure, wherein a plurality of zones of differing pore and interconnect sizes are obtained and wherein four different mechanisms are used in forming pore structure selected from the group consisting of:  
obtaining one or more emulsions providing Basic pores of controlled pore sizes approaching 0.1  $\mu$ m up to 0.5  $\mu$ m is obtained using very high emulsion deformation rate flows in which the flow is predominantly extensional and low emulsification temperature;  
obtaining one or more emulsions providing Basic pores of controlled a pore up sizes up to 300  $\mu$ m is obtained using emulsion deformation rate during mixing just above the critical deformation rate at which phase inversion takes place and high emulsification temperature;

generating Coalescence pores of large pore size up to 10,000  $\mu\text{m}$  is obtained by controlled pore coalescence of a Basic pore emulsion during polymerization;  
and providing Nano pores of nano-pore size up to 100 nm is obtained through adding a filler in the oil phase of a Basic pore emulsion and removing by solvent extraction after polymerization, and microcapillaries are obtained by polymerizing about a 3D network of fibers wherein a plurality of zones of differing pore and interconnect sizes are obtained by co-extrusion of polyhipe emulsions.

63. (currently amended) A~~The process of claim 62 for making a microcellular polyhipe polymer scaffold which further comprises polymerizing in a first stage the formation of obtaining at least one~~ a high internal phase emulsion (HIPE) of an immiscible dispersed phase in a continuous phase, wherein the dispersed phase is void or contains dissolved or dispersed materials, and (co)monomers, oligomers and/or pre-polymers are present in the continuous phase, by introducing the dispersed phase by controlled dosing into the continuous phase with controlled mixing at controlled emulsification temperature and rate to achieve at least one an emulsion of controlled pore size, and in a second stage subsequently homogenizing for controlled period under controlled deformation, in a third stage inserting a 3D network of fibres, and in a fourth stage polymerizing under controlled temperature and pressure, wherein controlled pore size of

wherein obtaining an emulsion is using a mechanism selected from:

obtaining one or more emulsions providing Basic pores of controlled pore size approaching 0.1  $\mu\text{m}$  up to 0.5  $\mu\text{m}$  is obtained using very high emulsion deformation rate flows in which the flow is substantially predominantly extensional and high low emulsification temperature;

obtaining one or more emulsions providing Basic pores of controlled pore size up to 300  $\mu\text{m}$  are is obtained using rate emulsion deformation rate during mixing just above the critical deformation rate at which phase inversion takes place, and high emulsification temperature;

~~generating Coalescence pores of large pore size up to 10,000  $\mu\text{m}$  are  $\mu\text{m}$  is obtained through the method of~~ by controlled pore coalescence of a Basic pore emulsion during polymerization;;

and ~~the providing Nano pores of nano-pore size up to 100 nm are is obtained through adding a filler in the oil phase of a Basic pore emulsion and removing by solvent extraction after polymerization and the, characterized in that~~ microcapillaries are ~~obtained~~ also formed by polymerizing about ~~the~~ a 3D network of fibers.

64. (currently amended) The process of claim 62 wherein the Coalescence ~~large~~ pore size up to 10,000  $\mu\text{m}$  is obtained by adding water soluble polymer to the emulsion aqueous phase or hydrophilic oils or filler solutes to the emulsion oil phase at elevated concentrations ~~with~~ providing controlled pore coalescence during polymerization

65. (currently amended) The process of claim 62 wherein the nano-pore size up to 100 nm is obtained ~~using~~ by combining in an emulsion an oil phase filler selected from high boiling point hydrocarbon oil, another monomer or macromonomer which does not undergo polymerisation, reactive or inert polymer and/or solid nano-size particles ~~optionally~~ with solvent extraction after polymerization.

66. (currently amended) The process of claim ~~62~~ 63, further comprising co-extruding polyhipe emulsions of differing pore and interconnect sizes.

67. (currently amended) The process of claim 65, wherein polyhipe emulsions ~~providing of~~ differing pore and interconnect sizes on polymerization are concentrically co-extruded.

68. (currently amended) The process of claim 65, wherein polyhipe emulsions ~~providing of~~ differing pore and interconnect sizes on polymerization are side-by-side co-extruded.

69. (currently amended) The process of claim 62, further comprising using multiple-feed points to reduce extensional deformation, during dosing period of emulsification stage with a prolonged dosing to create a Basic a large pore emulsion providing a pore size up to 300  $\mu\text{m}$ .

70. (currently amended) The process of claim 62, wherein emulsification temperature is below or greater than 60C providing Basic pore size below or in excess of 60  $\mu\text{m}$ .

71. (currently amended) The process of claim 62, wherein the homogenisation temperature is in the range of 60 – ~~to~~ 150°C.

72. (currently amended) The process of claim 62, and further ~~using~~ combining in an emulsion an additional aqueous or oil phase initiator, cross-linking agent or filler.

73. (currently amended) The process of claim ~~62~~ 72, and further ~~using~~ combining in an emulsion an additional oil phase filler to reduce amount of cross linking agent and reduce effective viscosity for emulsifying and homogenising, optionally leaching out after polymerization to create nanopores.

74. (previously presented) The process of claim 62, wherein the emulsion comprises aqueous and non-aqueous phases.

75. (currently amended) A microcellular polyhipe polymer scaffold having pores and interconnects made by the process of Claim 62 which comprises a polymerized high internal phase emulsion (HIPE) of a plurality of co-extruded polyhipe emulsions, forming four different zones of polymer selected from:

a zone of polymer having controlled Basic pores of size approaching 0.5  $\mu\text{m}$ , a zone of polymer having controlled Basic pores of size up to 300  $\mu\text{m}$ , a zone of polymer having Coalescence pores of size up to 10,000  $\mu\text{m}$ , and a zone of polymer having nano-pores of nano-pore size up to 100 nm.

~~suitable for growth of living~~

~~matter for biomedical applications, made by the process of claim 61-62, which comprises a homogeneous cross linked open cellular material defined by a bulk polymer matrix having a surface and an interface with an internal phase, and having porosity greater than 75% comprising emulsion derived pores of diameter in the range of 0.1 to 10,000 micron and emulsion derived pore interconnects of diameter in the range of up to 100 micron, wherein the scaffold comprises a plurality of discrete zones with location selected from:~~

~~at the polymer surface;~~

~~within its bulk matrix;~~

~~at the interface between polymer and internal phase; and~~

~~between adjacent but distinct pores or interconnects,~~

~~having a form and dimension of pore and interconnect type within each zone, and location of zones wherein adjacent zones are distinguished by boundaries, whereby zones are suitable for regulating positioning and morphology of living matter, wherein the scaffold comprises controlled pore sizes selected from the range up to 0.5  $\mu\text{m}$ , up to 300  $\mu\text{m}$ , up to 10,000  $\mu\text{m}$ , and up to nm size and comprises pore interconnects selected from the range up to 100 micron, and approaching 500 micron, and wherein the scaffold comprises pore and interconnect sizes in different ranges in two or more distinct zones~~

76. (currently amended) The microcellular polyhipe polymer scaffold of claim 75, wherein the distinct zones are discrete or interpenetrating.

77. (currently amended) The microcellular polyhipe polymer scaffold of claim 75, wherein microcapillary networks are present within the emulsion derived pores.

78. (currently amended) The microcellular polyhipe polymer scaffold of claim 75, which comprises more than one type of microcapillary.
79. (currently amended) The microcellular polyhipe polymer scaffold of claim ~~75~~8, wherein each microcapillary type is distinguished by diameter, surface modification, interface porosity or pore size or chemical structure
80. (currently amended) The microcellular polyhipe polymer scaffold of claim 75, wherein emulsion derived pores comprise nanoporous walls which are void, increasing the size of interconnects or which contain filler polymers for extra strength.
81. (currently amended) The microcellular polyhipe polymer scaffold of claim 75, wherein the scaffold is suitable for growth of living matter selected from cells, micro-organisms such as bacteria and virus and mixtures thereof.
82. (currently amended) The microcellular polyhipe polymer scaffold of claim 75, which comprises micro channels formed of pores with interconnects suitable for providing communication and penetration of living matter for anisotropic (directional) growth thereof.
83. (currently amended) The microcellular polyhipe polymer scaffold of claim 75, wherein the walls of the micro-channels are biodegradable suitable for fusion of living matter in the biodegraded scaffold.
84. (currently amended) The microcellular polyhipe polymer scaffold of claim 75, which comprises ~~in~~-individual zones, pore and interconnect sizes in different ranges, suitable for co-culturing two or more types of living matter.

85. (currently amended) The microcellular polyhipe polymer scaffold of claim 75, wherein the ratio of interconnect to pore diameter is in the range  $0 < d/D < 0.5$ , when the pore diameter is less than about 200 microns.

86. (currently amended) The microcellular polyhipe polymer scaffold of claim 75, ~~which comprises extensive networks of elongate microcapillaries obtainable by molding about fibrous inserts of diameter in the range from 10 micron up to 1000 micron, throughout the scaffold or zones thereof, separated by the microcellular polymer wherein~~ microcapillaries are suitable for blood or nutrient supply channels, expression channels for living matter and seeding of living matter.

87. (currently amended) The microcellular polyhipe polymer scaffold of claim 75, wherein the interface between a microcapillary wall and the bulk polymer provides a thin surface layer of the order of 0.5 to 5 ~~microns~~  $\mu\text{m}$ , forming a zone particularly suited for directional (anisotropic) growth of living matter.

88. (currently amended) The microcellular polyhipe polymer scaffold of claim ~~75~~87, wherein the interface has smaller pore size than the bulk polymer wherein the zone is suitable for growth of cells forming a lining, for example cells lining the blood vessels or for growing endothelial cells on the interface surface.

89. (currently amended) The microcellular polyhipe polymer scaffold of claim 75, which comprises a module of shell and tube type or cubic/polyhedral type with respect to direction and/or configuration of channels and/or microcapillaries.

90. (currently amended) The microcellular polyhipe polymer scaffold of claim 75, which comprises a surface coating, using coating materials introduced to an emulsion in situ during polymerization or post polymerization

91. (currently amended) The microcellular polyhipe polymer scaffold of claim 75, wherein polymer is selected from the group consisting of proteins and cellulose,

polyacrylamide, polyvinyl in rigid or flexible form, poly(lactic acid), poly(glycolic acid), polycaprolactone, poly (lactide/glycolide) and polyacrylimide.

92. (currently amended) The microcellular polyhipe polymer scaffold of claim 75, wherein the polymer comprises resiliently deformable or elastic material or is rendered resiliently deformable or elastic and is suitable for repeated stress and relaxation by means of oscillatory straining of the scaffold during cell growth facilitating rate of cell growth.

93. (currently amended) The microcellular polyhipe polymer scaffold of claim 75, wherein the polyhipe scaffold is electrically conductive or is rendered electrically conductive whereby it is suitable for conducting an electric current during cell growth, facilitating distinguishing certain cell types and promoting growth and fusion of particular cell types.

94. (currently amended) A biologically active system comprising a polyhipe scaffold made by the process of claim 26 62 and living matter providing normal cell functioning associated with a natural biologically active system present in the human or animal body, wherein living matter is selected from the group consisting of microorganisms or multiple cells selected from human, animal and plant cells.

95. (currently amended) The biologically active system of claim 94, wherein the living matter is selected from the group consisting of isotropic tissue, bone cells, anisotropic cells, fibroblasts, chondocytes, osteoblasts, bone marrow cells, hepatocytes, cardiomyocytes, neurons, myoblasts, macrophages and microvascular endothelium cells.

96. (currently amended) The biologically active system of claim 95, wherein the isotropic tissue is obtained from cartilage, cornea or marrow.



97. (currently amended) The biologically active system of claim 95~~4~~, wherein the anisotropic cells are nerve, muscle, or blood vessel cells or blood vessel or organ lining cells.

98. (previously presented) A method for making the biologically active system of claim 94, which comprises providing cells on or in the polyhipe scaffold in a controlled environment and providing a suitable nutrient adapted for growth and providing conditions for growth promotion and positional control.

99. (previously presented) biologically active system of claim 94, wherein the system is an implant or a module that mimics a part of the human or animal body or for use in a growth environment.

100. (currently amended) The biologically active system of claim 99~~4~~, wherein the implant or the module is a contact lens, a dental filling, a cochlea implant, a vascular support, or a skin patch.

101. (currently amended) The biologically active system of claim 99~~4~~, wherein the implant or the module is an organ support module suitable for growth of specific organ cells in the polyhipe scaffold.

102. (new) The process of claim 62 wherein microcapillaries are obtained by polymerizing about a 3D network of fibers.

103. (new) The process of claim 62, which comprises providing at least one polyhipe emulsion, and additionally providing a mould including inserts such as rods or fine fibres, pumping polyhipe emulsion and optional filler into the mould about the inserts and polymerising to provide pores and interconnects, with subsequent removal of inserts to provide microcapillaries and optional removal of filler to provide nano-pores.

104. (new) A microcellular polyhipe polymer scaffold having pores and interconnects made by the process of Claim 63 which comprises a polymerized high internal phase emulsion (HIPE) of at least one polyhipe emulsion, forming any of four different zones of polymer selected from the group consisting of:

a zone of polymer having controlled Basic pores of size approaching  $0.5\ \mu\text{m}$ , a zone of polymer having controlled Basic pores of size up to  $300\ \mu\text{m}$ , a zone of polymer having Coalescence pores of size up to  $10,000\ \mu\text{m}$ , and a zone of polymer having nano-pores of nano-pore size up to  $100\ \text{nm}$ , additionally comprising microcapillaries.

105. (new) The biologically active system of claim 99, wherein the implant or module comprises a cubic or polyhedral module of closely interwoven but not interconnecting channels immersed in a polyhipe scaffold as made by and defined in Claim 62 or 63 and 75 or 104 suited for growth of specific organ cells in the polyhipe and/or the channels, wherein cells are optionally in contact with a specific microchannel and all cells are capable of intercellular communication.

106. (new) The process of claim 62, wherein pore and interconnect size are selected according to the type of cell to be grown and the type of growth, i.e. with or without penetration of the polymer, confined to a zone or between zones.

107. (new) The process of claim 62, additionally comprising providing a surface coating using coating material introduced to the emulsion in-situ or by post polymerization soaking and deposition.

108. (new) The microcellular polyhipe polymer scaffold of claim 104, wherein the zones are discrete or interpenetrating.

109. (new) The microcellular polyhipe polymer scaffold of claim 104, wherein microcapillary networks are present within the emulsion derived pores.

110. (new) The microcellular polyhipe polymer scaffold of claim 104, which comprises more than one type of microcapillary.
111. (new) The microcellular polyhipe polymer scaffold of claim 104, wherein emulsion derived pores comprise nanoporous walls which are void, increasing the size of interconnects or which contain filler polymers for extra strength.
112. (new) The microcellular polyhipe polymer scaffold of claim 104, wherein the scaffold is suitable for growth of living matter selected from cells, micro-organisms such as bacteria and virus and mixtures thereof.
113. (new) The microcellular polyhipe polymer scaffold of claim 104, which comprises micro channels formed of pores with interconnects suitable for providing communication and penetration of living matter for anisotropic (directional) growth thereof.
114. (new) The microcellular polyhipe polymer scaffold of claim 104, wherein the walls of the micro\_channels are biodegradable suitable for fusion of living matter in the biodegraded scaffold.
115. (new) The microcellular polyhipe polymer scaffold of claim 104, which comprises ~~in~~ individual zones, pore and interconnect sizes in different ranges, suitable for co-culturing two or more types of living matter.
116. (new) The microcellular polyhipe polymer scaffold of claim 104, wherein the ratio of interconnect to pore diameter is in the range  $0 < d/D < 0.5$ , when the pore diameter is less than about 200 microns.
117. (new) The microcellular polyhipe polymer scaffold of claim 104, wherein microcapillaries are suitable for blood or nutrient supply channels, expression channels for living matter and seeding of living matter.

118. (new) The microcellular polyhipe polymer scaffold of claim 104, wherein the interface between a microcapillary wall and the bulk polymer provides a thin surface layer of the order of 0.5 -5  $\mu\text{m}$ , forming a zone particularly suited for directional (anisotropic) growth of living matter.

119. (new) The microcellular polyhipe polymer scaffold of claim 104, which comprises a module of shell and tube type or cubic/polyhedric type with respect to direction and/or configuration of channels and/or microcapillaries.

120. (new) The microcellular polyhipe polymer scaffold of claim 104, which comprises a surface coating, using coating materials introduced to an emulsion in situ during polymerization or post polymerization

121. (new) The microcellular polyhipe polymer scaffold of claim 104, wherein polymer is selected from the group consisting of proteins and cellulose, polyacrylamide, polyvinyl in rigid or flexible form, poly(lactic acid), poly(glycolic acid), polycaprolactone, poly (lactide/glycolide) and polyacrylimide.

122. (new) The microcellular polyhipe polymer scaffold of claim 104, wherein the polymer comprises resiliently deformable or elastic material or is rendered resiliently deformable or elastic and is suitable for repeated stress and relaxation by means of oscillatory straining of the scaffold during cell growth facilitating rate of cell growth.

123. (new) The microcellular polyhipe polymer scaffold of claim 104, wherein the polyhipe scaffold is electrically conductive or is rendered electrically conductive whereby it is suitable for conducting an electric current during cell growth, facilitating distinguishing certain cell types and promoting growth and fusion of particular cell types.

124. (currently amended) A biologically active system comprising a polyhipe scaffold made by the process of claim 63 and living matter providing normal cell functioning associated with a natural biologically active system present in the human or animal body,

wherein living matter is selected from the group consisting of microorganisms or multiple cells selected from human, animal and plant cells.

125. (new) The process of claim 63, which comprises providing at least one polyhipe emulsion, and additionally providing a mould including inserts such as rods or fine fibres, pumping polyhipe emulsion and optional filler into the mould about the inserts and polymerising to provide pores and interconnects, with subsequent removal of inserts to provide microcapillaries and optional removal of filler to provide nano-pores.

126. (new) The process of claim 63, wherein pore and interconnect size are selected according to the type of cell to be grown and the type of growth, i.e. with or without penetration of the polymer, confined to a zone or between zones.

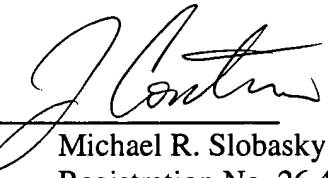
127. (new) The process of claim 63, additionally comprising providing a surface coating using coating material introduced to the emulsion in-situ or by post polymerization soaking and deposition.

If there are any questions, the Examiner is invited to call the attorney at 202-638-6666. Entry of the amendment and reconsideration is respectfully requested.

Respectfully submitted,

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